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10/563,276	01/04/2006	Nuno Miguel Simoes Dos Santos	VA/H-33271A	4311

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EXAMINER	
CORDERO GARCIA, MARCELA M	
ART UNIT	**PAPER NUMBER**
1654	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,276	DOS SANTOS ET AL.	
	Examiner	Art Unit	
	MARCELA M. CORDERO GARCIA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-71* is/are pending in the application.

4a) Of the above claim(s) *32-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-31 and 62-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the reply received on 3/26/09.

Any rejection from the previous office action, which is not restated here, is withdrawn.

Status of the claims

Applicant has amended claims 29-30, 32 and introduced new claims: 62-71. Claims 26-71 are pending in the application. Claims 32-61 are withdrawn as not drawn to the elected group/species. Claims 26-31 and 62-71 are presented for examination on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Barnes (WO 01/10459, cited in the IDS dated 4 January 2006).

Barnes discloses an isolated protein comprising the 55 kDa extracellular protein of *Photobacterium damselae subsp. piscicida.* Barnes discloses a vaccine comprising an extracellular 55 kDa protein of *Photobacterium damselae subsp. piscicida* for the prophylactic and/or therapeutic treatment of fish for infection by the organism *Photobacterium damselae subsp. piscicida* (e.g., page 1, lines 3-8; page 4, line 7 to page 7, line 35; page 16, line 7 to page 17, line 24; Figures 3 and 7). The newly

introduced limitation of claims 26 and 30 “apoptogenic” is met in page 16, lines 9-19 of Barnes.. With respect to claims 29 and 30, the limitation “immunogenic derivative” is inherently taught by a vaccine composition, e.g., in claim 10 and page 4, line 7 to page 5, line 22. The limitation of claims 31: "pharmaceutically acceptable carrier” is taught, e.g., claim 13. Applicant's source bacterium for the isolated protein is *Photobacterium damselae subsp. piscicida* and Barnes’ prior art reference also teaches that the isolated protein is from *Photobacterium damselae subsp. piscicida*. Applicant is claiming an isolated protein comprising the extracellular products of said bacterium, the prior art reference (Barnes) also teaches isolated protein comprising the extracellular products (ECP) of said bacterium. Applicant’s protein molecular weight is 55 kDa, Barnes’ protein molecular weight is also 55 kDa as evidenced by page 3 of the instant disclosure. Therefore, the structure of the protein, i.e., SEQ ID NO:2, as in the limitations of claims 27 and 28 [drawn to SEQ ID NO: 2 and to “having” amino acid residues 17 through 513 of SEQ ID NO: 2], are deemed inherent to the prior art composition which is obtained from the same species (*Photobacterium damselae subsp. piscicida*), the same region within such species (extracellular) and has the same molecular weight (55 kDa) as the claimed composition. Please note that with regards to the term “having” the MPEP at section 2111.03 indicates that “[t]ransitional phrases such as “having” must be interpreted in light of the specification to determine whether open or closed claim language is intended”. In the instant case, the disclosure does teach that the term “having” may include other residues, and therefore reads upon an open transitional phrase (e.g., page 5, last paragraph). It is noted that the Patent and Trademark Office

is not equipped to conduct experimentation in order to determine whether Applicants' SEQ ID NO: 2 (within the claimed 55 kDa extracellular protein of *Photobacterium damselae subsp. piscicida* composition) differs and, if so, to what extent, from that of the discussed reference (Barnes). Therefore, the reference is deemed to anticipate the instant claims above, and the burden of establishing non-anticipation by objective evidence is shifted to the Applicants.

Applicant's arguments

The Office rejected claims 26-31 as allegedly anticipated by Barnes (WO 01/10459). Office Action at page 2-4. In view of the tbregoing amendment and the following remarks, the rejection is traversed.

According to the Office, "Barnes teaches an isolated protein comprising the 55 kDa extracellular protein of Photobacterium darnselae subsp. Piscicida." Office Action at page 3, lines 1-2. Moreover, the Office asserts that "the structure of the protein, i.e., SEQ ID NO:2 ... is deemed inherent to the prior art composition which is obtained from the same species (Photobacterium damselae subsp. Piscicida), the same region within such species (extracellular) and has the same molecular weight (55 kDa) as the claimed composition." Office Action at page 3, lines 16-21. According to the Office, "the burden of establishing non-anticipation by objective evidence is shifted to the Applicants." Office Action at page 4, lines 3-5.

Applicants point out that, in addition to the above passages from Barnes cited by the Office, Barnes also states that "[s]ubsequent purification of the 55 Kda protein and sequencing have revealed three proteins in this region." Barnes at page 16, lines 23-25. According to Barnes' sequencing experiments, one protein is N-terminal blocked ... and, therefore unable to obtain a sequence, however this fraction has strong Haemagglutinating activity." Barnes at page 16, lines 25-29. As to the second and third proteins, Barnes specifically discloses their respective N-terminal sequences, however, neither sequence corresponds to Applicants' isolated protein. Barnes at page 16, lines 30-35. Even with respect to size, Barnes teaches that of the two bands evident, "one [ran] close to 97Kda" and "[t]he other was smaller, running close to, but below, the 55KDa marker." Barnes at page 13, lines 7-11. Therefore, the identity of the protein disclosed in Barnes is unclear.

Indeed, regarding the Office assertion that "the structure of the protein, i.e., SEQ ID NO:2 ... is deemed *[inherent]* to the prior art composition," Applicants point out that inherency cannot be established by mere possibilities or even probabilities. The fact that

a certain result or characteristic may occur or may be present in cited art is not sufficient to establish the inherency of that result or characteristic. MPEP §2112. Barnes was unable to sequence one of three proteins that apparently were co-migrating *(i.e.,* "running close to, but below, the 55KDa marker"). Barnes at page 13, lines 10-11. And of the other two proteins that were in fact sequenced by Barnes, neither one corresponds to Applicants' sequence.

Then, although it is not clear what protein is disclosed in Barnes, it is clear that Applicants' claimed protein is distinct from the protein disclosed in Barnes. The instant specification, at page 3, lines 16-18, states that "[t]he 55kDa protein of the present invention is distinct from the so-called 55kDa ECP protein complex ... disclosed in [Barnes], which in fact is nearer to 52kDa in size." Further, as it relates to apoptogenic properties, the instant specification further points out at page 3, lines 22-25 that, "when antiserum raised against the [Barnes] 55kDa ECP complex was used to treat ECP preparations to remove this protein, the apoptogenic properties of the treated ECP preparation were unaffected." Applicants point out that the 55kDa protein of the present invention has apoptogenic properties and is distinguishable by apoptosis assays such as that referenced by the instant specification at page 6, last line through page 7, line 3 ("A skilled person can easily test for absence of this protein in a strain by ... replicating the apoptosis assay described in do Vale *et al.,* Fish and Shellfish Immunology 15 (2003) 129-144.").

Response to Applicant's arguments

Applicant's arguments set forth above have been fully considered but they are not persuasive for the reasons of record, the reasons set forth above and for the following reasons:

1) .With regards the arguments that the Barnes protein is "in fact nearer to 52 kDa" in size, Applicant has not provided any specific evidence besides a conclusory statement. There is no data that provides a comparison of the protein from Barnes identified as a 55 kDa ECP or the specific conditions used by Applicant to measure the protein disclosed by Barnes as a 55 kDa protein and the 55 kDa protein of the instant application. It is known in the art that measurement of molecular weights by SDS-PAGE gels as taught by Barnes does carry uncertainty as it relies in visual identification of bands. Further, Applicant has not, e.g., sequenced Barnes' protein, which would clearly

point away from the instant inherency rejection. “[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.” (MPEP section 2112). “There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference.” (MPEP 2112-II). In the instant case it appears that Applicants have sequenced a protein for which its sequence was previously unknown. The source from which it is obtained and the reported molecular weight of the protein of Barnes and of the protein of the instant invention are the same.

2) With respect to the limitation ‘apoptogenic’ please note that this limitation does not expressly state with respect to what is the protein is apoptogenic. Barnes teaches that "Antisera raised in sea bass against the 97 kDa OMP cross reacted with the 55 kDa ECP. Similarly, Antibodies raised in sea bass against the 55 Kda ECP also cross reacted with the 97 OMP.” (page 16, lines 9-19). Please note that the disclosure appear to teach that the 55 kDa is apoptogenic with respect to the 97 kDa proteins in Barnes. T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. (MPEP 2112-V). In the instant case Applicant has not conclusively proven that the protein of Barnes is different from that of the instant invention especially because the 55 kDa protein of Barnes seems to also as set forth above. Although Applicant has provided a method to measure apoptosis, it has not provided specific evidence regarding the Barnes and the

instant protein with respect to the generic apoptogenic limitation as instantly claimed (i.e., the claims are drawn to apoptogenic behavior of any kind, as it is not specified apoptogenic with respect to what). See also pages 13-14 of Barnes.

New grounds of rejection necessitated by Applicant's new claims

Claims 62-71 are rejected under 35 U.S.C. 102(b) as being anticipated by Barnes (WO 01/10459, cited in the IDS dated 4 January 2006).

The limitations of claim 62-71 are also taught inherently by Barnes, for the reasons set fort above and because the structural limitations of the claim are met, i.e., an isolated polypeptide that is homologous or a substantially homologous recombinant derivative of a Photobacterium damselae subsp. Piscida 55 kDa extracellular protein or fragment thereof. Please note that the term "recombinant" is not deemed to impart any specific structural limitations in the structure, since the disclosure does not have a closed definition for what a recombinant derivative is (see page 5, last paragraph) and because natural sequences can be made via recombinant methods. Although one embodiment of the recombinant derivative may have glycosylation, such limitation is not encompassed by the instant claims as drafted. See also page 6, paragraphs 1-2. and pages 5, 7-8 and 16. Therefore the protein of Barnes is still deemed to read upon claim 62. With respect to .the terms "homologous" and "substantially homologous", the instant specification discloses that "[t]he invention encompasses derivatives being nucleic acid sequences and amino acid sequences which are substantially homologous to the sequences provided in SEQ ID NO:1 and SEQ ID NO:2, respectively. "Substantially homologous" means that a sequence, when compared to a reference sequence, has at

least 50% homology, more preferably at least 60% homology, more preferably at least 70% homology, more preferably at least 80%, 85%, 90%, 95%, 98% or greater homology to the reference sequence. However, there is no express definition of homologous. Therefore one skilled in the art would understand it to not be limited to 60% homology. Other limitations have been addressed one-by-one in the rejection and response to arguments above. Therefore the reference is deemed to anticipate the claims above.

Claim 62 is rejected under 35 U.S.C. 102(b) as being anticipated by Edwards (US 6,087,336).

Please note that the claims are also drawn to fragments. Edwards discloses, for example, peptides Arg-Ala-Ala-Ala-Val (SEQ ID NO:46), Arg-Ala-Ala-Ala-Thr (SEQ ID NO:47) which read upon a fragment of the instant claims because they are homologous and/or substantially homologous derivatives of the fragment of *Photobacterium damselae subs. Piscida* 55 kDa, Thr-Ala-Ala-Ala-Thr, residues 69-73 of SEQ ID NO: 2) The instant disclosure addresses fragments as follows: The sequences of the invention include fragments of the reference nucleic acid sequence. A "fragment" of the 55 kDa protein nucleic acid reference sequence is any part of that sequence comprising at least 10, preferably at least 20, more preferably at least 30, more preferably at least 50, optionally at least 75, or at least 100 consecutive nucleotides." Therefore it necessitates at least 4 amino acids. The compounds of US 6,087,336 meet all the structural limitations required by the claim. The term "recombinant" has been discussed above, and again, based on the disclosure it does not impart any specific structural

limitation to the claim since USPTO personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. Limitations appearing in the specification but not recited in the claim should not be read into the claim (see MPEP 2106). Therefore the reference is deemed to anticipate the instant claim above.

Conclusion

No claim is allowed. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCELA M. CORDERO GARCIA whose telephone number is (571)272-2939. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MMCG 08/09